REMARKS

Claims 1-27 were pending in the subject application. Applicants have amended claims 12 and 18 to correct typographical and grammatical errors. After entry of this amendment, claims 1-27 will be pending.

The 35 USC 112, first paragraph, rejection

The Examiner rejected claims 9 through 14 and 18 through 27 under 35 USC 112, first paragraph, for being directed to subject matter assertedly not enabled in the specification. The Examiner admitted at page 2 of the office action that the specification enables compositions including zinc, anti-angiogenic agents and anti-cancer agents but alleged that the specification "does not reasonably provide enablement for all compounds being different than tetraalkylammonium tetrathiomolybdate compound." In an analysis of factors espoused in *In re Wands*, the Examiner asserted (i) unpredictability of pharmaceutical and chemical art is high, (ii) the claims are broad and encompass a composition of tetraalkylammonium tetrathiomolybdate and any agent that is different from tetraalkylammonium tetrathiomolybdate, (iii) the specification provides guidance "and is only enabled for adding angiogenic and anticancer agents to tetraalkylammonium tetrathiomolybdate," (iv) the examples are drawn to the combination of tetraalkylammonium tetrathiomolybdate and zinc and "a few anticancer drugs," and (v)

> "since the compound structure and activity for each pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to obtain all pharmaceutical compositions by adding an agent to tetraalkylammonium tetrathiomolybdate. The applicants disagree.

The Examiner's analysis of *Wands* factors considered to be relevant is in one instance factually incorrect, and the applicants submit that when the relevant factors espoused in *Wands* are properly assessed, it must be concluded that the subject matter of the claims is enabled by the specification.

First, the Examiner has misconstrued the breadth of the claims. The composition of claim 9 comprises, *inter alia*, a tetraalkylammonium tetrathiomolybdate compound (as recited in claim 1) or tetrapropylammonium tetrathiomolybdate (as recited in claim 5) and a therapeutic agent different from the tetraalkylammonium tetrathiomolybdate compound (or where dependent on claim 5 the tetrapropylammonium tetrathiomolybdate compound). Claim 18, as amended, is directed to a kit comprising at least one tetraalkylammonium tetrathiomolybdate compound and at least one therapeutic agent that is different from said tetraalkylammonium tetrathiomolybdate compound. The term "therapeutic agent" does not, as the Examiner stated; embrace "any agent that is different from tetraalkylammonium tetrathiomolybdate compound" or "all compounds being different than tetraalkylammonium tetrathiomolybdate compound." Therapeutic agents are by definition compounds that have been shown to have some therapeutic effect, and those of ordinary skill in the art would readily understand that not every compound or agent that is not a tetraalkylammonium tetrathiomolybdate has a therapeutic effect. The applicants submit that therapeutic agents are well known in the art and continue to be identified (see the Table of Contents and the Brand and Generic Name Index of the 55th Edition of the Physician's Desk Reference (2001), made of record as Reference C155 of the Supplemental Information Disclosure Statement submitted herewith). These compounds are only a subset of all compounds/agents that are not tetraalkylammonium tetrathiomolybdate.

Second, the examiner's admits that guidance in the specification enables making and using compositions including angiogenic and anti-cancer agents, but fails to explain why this guidance cannot be utilized by the worker of ordinary skill to make and use compositions comprising other therapeutic agents. The applicants submit a copy of the 12th Edition of the World Health Organization's Essential Medicines List (April 2002, http://www.who.int/medicines/publications/essentialmedicines/en/index.html) which lists numerous examples of combinations of therapeutic agents (see *inter alia*, §6.2.2. Other antibacterials, §6.4.2 Antiretrovirals, and §6.5.3 Antimalarial medicines) (made of record as Reference C156 of the Supplemental Information Disclosure Statement submitted herewith). Reference C156 shows that combinations are routinely practiced in the medical arts and one of ordinary skill could easily apply the teachings in the specification showing how to prepare

the exemplified compositions for preparation of any other composition including a tetraalkylammonium tetrathiomolybdate and a therapeutic agent.

The Examiner cited a statement in *In re Dreshfield* 110 F.2d 235 (CCPA, 1940) as purportedly supporting the position taken with respect to the amount of guidance provided in the specification, but the Examiner did not show, however, that the facts in *Dreshfield* were on point with the instant facts. Nonetheless, the cited statement in part reads "it must appear in the applicant's specification... that the chemicals or chemical combination included in the claims are capable of accomplishing the desired result." With the therapeutic benefit from a tetraalkylammonium tetrathiomolybdate compound disclosed and demonstrated in the specification, and the therapeutic effect ascribed to the "other" compound that is not a tetraalkylammonium tetrathiomolybdate having been demonstrated and known in the art thereby allowing for the compound to be considered therapeutic, there can be no doubt that a composition within the scope of the claims will accomplish the desired therapeutic result. Thus, regardless of the asserted unpredictability in the chemical arts, the therapeutic agents cited for the claimed compositions will each have proven, and therefore predictable, effects.

Lastly, the Examiner's assertion that preparation of all pharmaceutical compositions within the scope of the claims would require "painstaking experimental study" is unsupported by any evidence. No one can dispute that it would require preparation of many formulations, should a worker of ordinary skill decide to prepare every composition within the scope of the claims for some unusual reason, but nothing about the time or quantity considerations implies this would be painstaking. Regardless, time and quantity of experimentation are not necessarily controlling in assessing whether experimentation is undue. The Examiner is referred to MPEP 2164.06 which states,

> "'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this

consideration and are not the controlling factors. *United States v. Telectronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989).

Moreover, applicants point out that there is no basis to expect or predict that the addition of a second therapeutic agent would be detrimental to the benefit afforded by the tetrathiomolybdate compound. Therefore, one skilled in the art would understand from the subject application that the combination of a tetrathiomolybdate and another therapeutic agent would be useful.

The applicants therefore submit that a proper analysis of the *Wands* factors clearly shows that the full scope of the invention can be practiced without undue experimentation and as a result, the rejection of claims for asserted lack of enablement must be withdrawn.

The obviousness-type double patenting rejection

The applicants acknowledge the rejection of the subject matter of claims 1 through 27 for assertedly being obvious over the subject matter of claims 1 through 89 in US Patent 7189865. The applicants will address this issue upon a finding that all currently pending claims are otherwise in condition for allowance.

CONCLUSION

In view of the remarks made herein, the applicants believe that all statutory rejections have been overcome and notification of the same is requested.

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Respectfully submitted,

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